IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

| | | |
|---|---|---|
| RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased, | ) | |
| Plaintiff, | ) | Civil No. 3:05-0444 |
| | ) | Judge Aleta A. Trauger |
| v. | ) | (Dist. Of MA No. 1:05-cv-11515PBS) |
| PFIZER, INC., *et al.*, | ) | |
| Defendants. | ) | |

**DEFENDANTS' OPPOSITION TO PLAINTIFF'S**
**MOTION TO EXCLUDE THE TESTIMONY OF SHEILA WEISS SMITH, PH.D.**

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

### CASES



### STATUTES

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") hereby respond to Plaintiff's motion *in limine* to exclude the testimony of Sheila Weiss Smith. Plaintiff tries to exclude Dr. Weiss Smith's testimony by criticizing her qualifications in areas *outside* her designated areas of expertise. This straw-man attack is irrelevant to the scientific merit of Dr. Weiss Smith's methodologies and her undeniable expertise in epidemiology, pharmacoepidemiology, and pharmacovigilance/drug safety. (Dr. Weiss Smith has a Ph.D. in epidemiology from Johns Hopkins University; she is a full professor at a major university and has served on various FDA Advisory Committees and as a visiting scientist at NIH.) Plaintiff distorts the record and seeks to exclude opinions that are far beyond those Dr. Weiss Smith actually offered in her expert reports. Rather than addressing Dr. Weiss Smith's substantive opinions, Plaintiff vaguely tries to exclude "many" of her opinions. Ironically, Plaintiff's argument on Dr. Weiss Smith's qualifications only highlights the defects in her own expert's proffered testimony. Under the settled standards of Federal Rule of Evidence 702 and *Daubert*, Plaintiff's objections to mathematical and typographical errors in Dr. Weiss Smith's expert reports provide no basis for exclusion. They merely go to the weight a jury should give her opinions, not their admissibility. Her expert testimony is admissible.

## I. DR. WEISS SMITH IS WELL QUALIFED TO RENDER THESE OPINIONS ON THE EPIDEMIOLOGY AND PHARMACOEPIDEMIOLOGY OF NEURONTIN

### A. Dr. Weiss Smith's Expert Opinion Aligns with Her Professional Expertise

Defendants offer Dr. Weiss Smith as an expert in epidemiology, pharmacoepidemiology, and pharmacovigilance/drug safety. Her education, training, and professional history easily qualify her as an expert in these scientific disciplines. But, in her motion, Plaintiff tries to keep Dr. Weiss Smith from testifying due to her lack of expertise in areas in which she was not designated. Defendants will not call Dr. Weiss Smith to offer opinions regarding a) clinical interpretation of safety information, b) regulatory requirements, c) compliance with labeling regulations, d) suicidology, e) adequacy of Defendants' NDA

submissions, f) adequacy of Defendants' periodic safety reports for Neurontin, or g) adequacy of Defendants' pharmacovigilance practices. Instead, she will be called to opine within her areas of expertise - epidemiology, pharmacoepidemiology, and pharmacovigilance/drug safety - as each pertains to Neurontin. Specifically, she will testify that:

1) Plaintiff's expert uses flawed methodology in reaching her conclusion of a causal relationship between Neurontin and suicidality;

2) The Neurontin post-marketing adverse data show no evidence of a statistical signal between Neurontin and suicide or suicide attempt;

3) The post market adverse event data can not be used to establish a causal relationship between Neurontin and suicide or suicide attempt;

4) Based on her own analysis of the FDA AERS database, Dr Weiss Smith found there is no signal of disproportionate reporting of completed suicide or suicide attempt for Neurontin;

5) Plaintiff's experts' analytic methods are inappropriate for postmarketing safety analysis and Plaintiff's interpretation of the postmarketing adverse event data is flawed and deviates from generally accepted concepts in pharmacoepidemiology;

6) The product labeling regarding suicide accurately reflected the safety information that was available during the relevant time period.

(*See* Ex. A, Sheila Weiss Smith, Ph.D., November 4, 2008, Report.)[1] Plaintiff has little to say about *these* opinions. Instead, she tries to disqualify Dr. Weiss Smith by attacking phantom versions of her opinions. In so doing, Plaintiff conspicuously avoids addressing the substance of Dr. Weiss Smith's actual opinions and qualifications.

Dr. Weiss Smith's credentials speak for themselves. As set forth fully in her CV, (*see* Ex. B, Sheila Weiss Smith, Ph.D., Curriculum Vitae), Dr. Weiss Smith is a Professor in the Departments of Pharmaceutical Health Services Research, School of Pharmacy and Epidemiology & Preventive Medicine, School of Medicine, University of Maryland Baltimore, and a visiting scientist at the National Institutes for Health (NIH). Over the past decade, she has

[1] All exhibits are attached to the accompanying Declaration of Mark S. Cheffo.

served as a voting member on a number of FDA advisory committees, providing epidemiologic expertise on emerging drug safety issues, including assessing the need to revise product labeling. The University of Maryland recently named her Director of its new Drug Safety department. She works as a Research Associate at the Veterans' Administration and is a Visiting Professor in the Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health. A Fellow of the International Society of Pharmacoepidemiology, Dr. Weiss Smith completed a two-year postdoctoral fellowship in Pharmacoepidemiology & Regulatory Sciences at FDA and the University of Maryland and earned her Ph.D. in Epidemiology from Johns Hopkins University in 1996.

Dr. Weiss Smith's research efforts and writings focus on pharmacoepidemiology, and she has written extensively on the epidemiology of the safety risks associated with prescription medications, with a special emphasis on methodology. She is the Principal Investigator of a $500,000 grant on "the value of data mining," which comprehensively studies the validity of data mining algorithms in FDA's adverse reporting database, industry practices in data mining, and factors that influence the results of data mining.[2] She also has been Principal Investigator of two sequential National Cancer Institute contracts to look at the strength of the scientific evidence for cancer prevention and cancer promotion among commonly used medicines and nutraceuticals and to estimate their potential public health impact. Dr. Weiss Smith has participated as an investigator on several other grants studying data mining and pharmacoepidemiology.

Dr. Weiss Smith currently teaches "Advanced Topics in Pharmacoepidemiology," an

---

[2] Data mining is the use of statistical algorithms to quickly process large databases of adverse events to identify otherwise unexpected relationships between a drug and an adverse event (drug-event pairs) or a drug-drug interaction (drug-drug event). It differs from a scientific study, in that data mining is purely exploratory, whereas scientific studies are designed to test one or more predefined hypotheses. Any relationship determined, and hypothesis generated, through data mining is purely statistical; it may or may not be clinically meaningful. (Ex. C, Sheila Weiss Smith, Ph.D., December 20, 2007, Report at 21).

advanced level doctoral course taught simultaneously at the University of Maryland and FDA. She also teaches courses in epidemiology to pharmacy students and a course in pharmacoepidemiology at Johns Hopkins University. She regularly lectures in pharmacoepidemiology and epidemiology in courses at University of Maryland and Yale University.

Dr. Weiss Smith has served as a special government employee for FDA for more than a dozen years, and she has been a voting member of several FDA advisory committees. She reviews grant proposals for FDA, AHRQ, and EMEA, and peer-reviews submissions for a several prominent journals, such as Lancet, British Medical Journal, and PDS. She also sits on the editorial board of the Journal of Research in Social and Administrative Pharmacy and on the Isotretoin Scientific Advisory Board.

Without question, Dr. Weiss Smith has the necessary education, background and training to render expert opinions in the areas of epidemiology, pharmacoepidemiology, and pharmacovigilance/drug safety.

### B. Dr. Weiss Smith's Opinions Regarding Neurontin Labeling Only Address the Epidemiology Supporting the Labeling and Easily Fit Within Her Area of Expertise

Plaintiff contends that the Neurontin label did not adequately apprise physicians of the risk of suicidal behaviors. She bases this contention largely on Defendants' alleged failure to properly evaluate the clinical trial and post-marketing adverse events, which Plaintiff claims are "red flags" for suicidality associated with Neurontin. Dr. Weiss Smith's expert opinion shows why these "red flags" are illusory.

Defendants offer Dr. Weiss Smith to provide expert opinions on the epidemiology, pharmacoepidemiology, and pharmacovigilance data that form the bases for the Neurontin labeling. In essence, Dr. Weiss Smith's opinions, derived from methods well accepted in her fields of expertise, address whether the labeling appropriately reflected the available epidemiology, pharmacoepidemiology and pharmacovigilance data of suicidality. Her opinions

conclude that these data do not demonstrate an association between Neurontin and suicide and suicide attempts. Dr. Weiss Smith also opines that, based on her review of the epidemiologic and pharmacoepidemiologic evidence of suicidality, as well as her own analyses of the post-market data for Neurontin, the labeling accurately warned of the risks of suicidality. Her expert opinion does not require any expertise in the regulatory requirements for pharmaceutical labeling. Rather, it requires expertise in epidemiology, pharmacoepidemiology and pharmacovigilance, all of which Dr. Weiss Smith possesses.

Plaintiff's motion obscures Dr. Weiss Smith's significant experience reviewing labels and mischaracterizes her role as an expert in the labeling of Neurontin. (Pl.'s Memo. [90] at 5 (asserting that Dr. Weiss Smith "did not testify to any qualifications to evaluate the adequacy of a label and has never corresponded with the FDA concerning labeling").) Dr. Weiss Smith testified that she has participated in numerous groups that assessed labeling changes and, although she has not written to the FDA regarding labeling, she has interacted with the FDA regarding labeling. (*See* Ex. D, Sheila Weiss Smith, Ph. D., Dep. at 32:17-33:1.) Defendants do not offer Dr. Weiss Smith as an expert on the regulatory requirements for the labeling content of a pharmaceutical product or on Defendants' conduct in developing the Neurontin label.

## II. PLAINTIFF PROFFERS IRRELEVANT ARGUMENTS LAMENTING WHO DR. WEISS SMITH IS *NOT* AND WHAT RESEARCH SHE HAS *NOT* PERFORMED

Unable to pierce Dr. Weiss Smith's unassailable credentials as an expert pharmacoepidemiologist, Plaintiff tries to discredit her by cataloguing career paths she did not take and condemning her for not replicating the flawed analyses proffered by Plaintiff's experts. These arguments only undermine Plaintiff's own expert and provide no reasonable basis to exclude Dr. Weiss Smith from testifying.

### A. Dr. Weiss Smith's Expert Opinion Does Not Require Her To Be a Clinical Expert or "Suicidologist"

Plaintiff suggests that Dr. Weiss Smith's expert opinion is unreliable until she first makes herself a clinician and a "suicidologist." Plaintiff then tries to bolster this argument by misrepresenting Dr. Weiss Smith's testimony and criticizing her for using data that Plaintiff's own experts and FDA consider reliable. These arguments lack merit.

#### 1. Dr. Weiss Smith's Expertise in Pharmacoepidemiology Does Not Require Any Clinical Experience and Her Expert Opinion Does Not Draw on Any Clinical Expertise

Plaintiff first tries to silence Dr. Weiss Smith by complaining that she does not have any clinical experience or expertise. But her opinions do not require or rest upon any clinical expertise. Plaintiff ignores the glaring fact that Defendants did not name Dr. Weiss Smith, a Ph.D. in Epidemiology, as a clinical expert nor did Defendants ask her to provide opinions on clinical assessments. Rather, they named her as an expert in epidemiology, pharmacoepidemiology, and pharmacovigilance/drug safety. As such, she is providing opinions, based on scientifically sound methodologies, that the clinical trial and post-marketing data for Neurontin show no association or signal to suicide or suicide attempt. None of her expert opinions are shaped by her clinical judgment or clinical assessment of individual adverse events. They rest on her scientific and statistical analyses of composite data.

Plaintiff's argument also ignores well-established definitions of epidemiology, pharmacoepidemiology, and pharmacovigilance/drug safety, which illustrate why Dr. Weiss Smith's expertise and testimony are directly on point and necessary for the jury. The Reference Manual on Scientific Evidence defines epidemiologic evidence:

> Epidemiologic evidence indentifies agents that are associated with increased risk of disease in groups of individuals, quantifies the amount of excess disease that is associated with an agent, and provides a profile of the type of individual who is likely to contract the disease after being exposed to an agent. ***Epidemiology focuses on the question of general causation*** (i.e., is the agent capable of causing disease?) ***rather than that of specific causation*** (i.e., did it cause disease in a particular individual?).

Reference Manual on Scientific Evidence, 335-36 (2nd ed. 2000) (emphasis added). Pharmacoepidemiology is a branch of epidemiology that is "the study of the use and effects of medical products (drugs, biological product, and medical devices) in human populations." Sheila Weiss Smith, *Pharmacoepidemiology*, in *Encyclopedia of Epidemiology* (S. Boslaugh ed., Sage Publications, Inc. 2007). The FDA defines pharmacovigilance/drug safety as:

> [A]ll scientific and data gathering activities relating to the detection, assessment, and understanding of adverse events. This includes the use of pharmacoepidemiology studies. These activities are undertaken with the goal of identifying adverse events and understanding, to the extent possible, their nature, frequency and potential risk factors.

(Ex. H, FDA's March 2005 "Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepodemiologic Assessment" at 4.) These mainstream definitions plainly show that expertise in epidemiology, pharmacoepidemiology, and pharmacovigilance/drug safety does not require any clinical training.

**2. Dr. Weiss Smith Used Sound Pharmacoepidemiological Methods When Forming Her Opinion**

Dr. Weiss Smith's expertise in data mining, based upon her own assessment of the relevant data and literature on the pharmacoepidemiology of Neurontin and suicidality, qualifies her to offer opinions as an epidemiologist/pharmacoepidemiologist. Plaintiff misrepresents Dr. Weiss Smith's testimony by arguing she has "never designed pharmacovigilance procedures for a pharmaceutical company." (Pl.'s Memo. [90] at 7.) But Plaintiff fails to acknowledge that Dr. Weiss Smith will not be offered as an expert on Defendants' pharmacovigilance *practices or conduct*. Nor does Plaintiff mention that Dr. Weiss Smith has helped develop FDA guidance documents on pharmacovigilance and participated in the original draft of the guidance document that is now the March 2005 FDA Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment. (Ex. D, Weiss Smith Dep. at 99:11-22.) In fact, Plaintiff and her experts repeatedly rely upon this document, which they highlighted during the June 2008 *Daubert* hearing in the

MDL.

Plaintiff incorrectly suggests identification of a potential signal for suicidality universally requires clinical background and experience, by asserting that Dr. Weiss Smith lacks the proper qualifications to assess individual case reports or collections of case reports (i.e., case series) from post-market spontaneous data. (Pl.'s Memo. [90] at 10.) At her second deposition on December 22, 2008, Dr. Weiss Smith testified that as a pharmacoepidemiologist, she draws a distinction between a "signal of disproportional reporting" ("SDR") and a "signal," where the former is based purely on a statistical analysis of a database and the latter may be based on clinical review of case reports or case series. Neither the SDR nor the "signal" obtained through case review, standing alone, can establish the presence of an association between a drug and an adverse event. Results from analyses that find an SDR or a "signal" generate a hypothesis (not a conclusion) that may require further clinical evaluation and testing to determine if a true association exists. In responding to analyses purporting to identify a "signal" for Neurontin and suicidality that Plaintiff's experts sponsor, Dr. Weiss Smith has been crystal clear that a) Plaintiff's experts' methodology in identifying that signal are improper, and b) for her own analyses of the FDA AERS database, she is only addressing the presence of an SDR. However, it is important to remember that Dr. Weiss Smith's analysis of the FDA AERS database forms only a subset of the data she considered in forming her more global opinion that there is no association between Neurontin and suicidality. For her more global opinions, Dr. Weiss Smith considered the evidence commonly considered by epidemiologists (as described in the Reference Manual for Scientific Evidence), including such evidence as the peer-reviewed scientific literature, Neurontin clinical trial data, the regulatory submissions by Pfizer, and the FDA AED analysis. In evaluating these sources, Dr. Weiss Smith did not exercise any clinical judgment, nor was any such judgment required. Rather, Dr. Weiss Smith evaluated these sources from the perspective of an epidemiologist and pharmacoepidemiologist to determine whether there was any association

between Neurontin and suicidality.

Although she is not performing the clinical review herself, Dr. Weiss Smith has the expertise and training to evaluate whether other clinical experts' review of the Neurontin data is consistent with her own epidemiologic opinions concerning the absence of a potential association between Neurontin and suicide. For example, Dr. Weiss Smith relied on Pfizer's non-litigation summary of Neurontin data that were collected using a protocol that mirrored that used by FDA in its prior analyses of anti-depressant drugs. In 2005, FDA wrote to Pfizer:

> Based on our experience with the pediatric anti-depressant trials, the Division of Neuropharmacological Drug Products (DNDP) has developed a standard approach for evaluating drug-induced suicidality. Thus, we ask that you utilize the approach we have outlined in this letter for evaluating "possibly suicide related" adverse events occurring in placebo-controlled trials for gabapentin.

(Ex. E, Letter from Dr. Russell Katz to Manini Patel.) Dr. Weiss Smith's reliance on such materials as the non-litigation summaries of clinical trial data compiled by experts and clinicians at Pfizer in response to the FDA request and performed under an FDA-approved protocol, as well as the results of the randomized clinical trial data (which all experts agree do not show an association between Neurontin and suicidality), meet Rule 703's standard allowing experts to use "facts or data" that are of the "type reasonably relied upon by experts in the particular field." Fed. R. Evid. 703. Pharmacoepidemiologists typically rely upon such information including the regulatory submissions and summaries provided by Pfizer to the FDA when assessing potential associations between drugs and adverse events.[3]

Plaintiff's specious assertion that Dr. Weiss Smith should be precluded from relying on Pfizer's data summary of the Neurontin clinical trial data is belied by the fact that the FDA

---

[3] At page 11 of her memorandum, Plaintiff mischaracterizes Dr. Weiss Smith's testimony by omitting her review of data from the 1993 to 2000 time period, stating that because she did not review certain information about Defendants' pharmacovigilance activities during this period, she cannot opine as to absence of a signal for suicide. (Pl.'s Memo. [90] at 11.) However, Plaintiff ignores the fact that Dr. Weiss Smith's report extensively analyzed the FDA AERS data and related information for each year from 1993 through 2000, which does not require any knowledge of Defendants' conduct during that period. (*See* Ex. A, Sheila Weiss Smith, Ph.D., November 4, 2008, Report, Figures 1-11.)

uses these same data to analyze suicidality and anti-epileptic drugs ("AEDs"). (Ex. F, FDA's May 23, 2008, Statistical Review and Evaluation.) As the Court is well aware, in 2008, the FDA reviewed the clinical trial data for 11 AEDs, including Neurontin, for a potential signal for suicidality, and Plaintiff's experts rely heavily on the results of this analysis. Inexplicably, through the present motion, Plaintiff now implicitly criticizes Dr. Weiss Smith for considering and relying upon the same analysis of the Neurontin clinical trial data. Plaintiff cannot have it both ways. These data cannot simultaneously invalidate Dr. Weiss Smith's opinion and validate Plaintiff's experts' opinions regarding causation.

### 3. Dr. Weiss Smith's Level of Expertise in "Suicidology" Is Irrelevant to the Reliability of Her Analysis

Dr. Weiss Smith's level of expertise in "suicidology" is irrelevant to her analysis.[4] She analyzed data using fundamentally sound pharmacoepidemiologic principles, which do not require any expertise in "suicidality." Considering the scope of Dr. Weiss Smith's opinions and her stated areas of expertise, any lack of expertise in "suicidology" is not relevant.

In her full-time professional work, Dr. Weiss Smith regularly examines the FDA AERS database for potential safety issues. Here, she analyzed the Neurontin post-marketing data to respond to Dr. Blume, who uses anecdotal post-market adverse event reports to opine that Pfizer missed a signal of suicidality for Neurontin. Unlike Dr. Blume, however, Dr. Weiss Smith developed a protocol for analyzing the Neurontin data before performing any analysis. In doing so, she analyzed the data by selecting certain adverse events that, on their face, would meet the regulatory definition of "serious." Contrary to Plaintiff's assertions, this does not require any "clinical judgment." FDA regulations define "serious" cases as events that lead to death, hospitalization (initial or prolonged), life threatening, persistent, or significant disability, birth defect, or an important medical event that would have resulted in any of these outcomes if not for medical or surgical intervention. 21 C.F.R. § 314.80(a) (2009).

[4] Notably, Plaintiff's expert, Dr. Blume, is not an expert on "suicidology" either.

Plaintiff's expert, Dr. Blume, relies extensively on Neurontin post-market data. The FDA, however, considers such data unreliable for assessing any risk of suicidality with AEDs. Specifically, the FDA recognizes that for the purposes of studying a potential link between suicidality and antiepileptic drugs, post-marketing adverse event data are "uninterpretable":

> " . . . we have long ago decided that **postmarketing data are not the right data to look at**, or we don't believe that for these sorts of things where there is a high background rate of suicidality so defined in these populations, I think we have concluded that **postmarketing data is uninterpretable**, and that is why we went to placebo-controlled trials."

(Ex. G, July 10, 2008, FDA Advisory Comm. Meeting Tr., at 103 (emphasis added).) Dr. Blume's opinions ignore these important limitations.

Given the limitations and biases inherent in post-market data, Dr. Weiss Smith properly decided to focus her analysis on the terms "completed suicide" and "suicide attempt" to maximize her chances of only studying "serious" events. This decision is epidemiologically and pharmacoepidemiologically sound because the terms "completed suicide" and "suicide attempt" are unambiguous and indisputably "serious" under the applicable regulatory definition. Using these terms, Dr. Weiss Smith found that there was no signal of disproportional reporting of "completed suicide" or "suicide attempt" for Neurontin compared to all other drugs.

Yet Plaintiff criticizes Dr. Weiss Smith's use of these terms, asserting that she should have included broader terms such as "suicidal ideation." Dr. Weiss Smith realizes that terms like "suicidal ideation" are not necessarily linked to "serious" events and, given the vagaries of adverse event reporting, would not reliably distinguish "serious" and non-serious cases. Dr. Weiss Smith used her training and expertise in pharmacoepidemiology and data mining to limit her analysis to two terms: "completed suicide" and "suicide attempt." While Plaintiff is free to challenge her methodology through cross-examination, Dr. Weiss Smith's analysis is fundamentally sound, does not depend on any expertise in suicidality, and should not be excluded.

### B. Dr. Weiss Smith Does Not Have To Replicate Plaintiff's Experts' Work To Offer Her Own Expert Opinion

#### 1. Dr. Weiss Smith's Reluctance To Consider Plaintiff's Counsel's Alternate Theories Does Not Make Her Opinion Unreliable

Plaintiff makes the far-fetched assertion that because Dr. Weiss Smith did not consider an alternative explanation proposed by Plaintiff's counsel, her opinions are somehow no longer based on sound scientific methodology. At her deposition on December 22, 2008, Plaintiff's counsel, Mr. Altman, presented Dr. Weiss Smith with a plot that he himself had developed for this litigation. It purports to show a higher rate of "suicidal and self-injurious behavior"[5] events for "psychiatric conditions" versus other indications for which Neurontin was taken. Dr. Weiss Smith opined that the potential higher rate of "suicidal and self-injurious behavior" events Mr. Altman observed in the psychiatric population could be the result of "confounding by indication," i.e., the increased rate of "suicidal and self-injurious behavior" is an inherent risk in the psychiatric population, regardless of the medications ingested. The FDA recognizes confounding by indication and it is well-established in epidemiologic literature. (Ex. H, FDA's March 2005 "Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepodemiologic Assessment.") Dr. Weiss Smith made it clear that this was one possibility. (Ex. D, Weiss Smith Dep. at 289:16-21.) Mr. Altman suggested only one other "possible explanation" for the results depicted in the plot: a lack of efficacy of Neurontin. Contrary to Plaintiff's assertions, Dr. Weiss Smith did not "categorically" dismiss this possibility. Rather, she testified that the possibility was "way beyond" what she could glean from the plot, as counsel did not provide her with any foundational information regarding efficacy or concomitant medications. (Ex. D, Weiss Smith Dep. at 290:14-18.) It is unclear how Dr. Weiss Smith's reluctance to instantly accept Plaintiff's counsel's incomplete

[5] The term "suicidal and self-injurious behavior" is what is known as a "higher level term" in the adverse event coding dictionary MedDRA. It broadly includes the terms completed suicide, intentional self-injury, self injurious behavior, self-injurious ideation, suicidal behavior, suicide ideation, and suicide attempt.

hypothetical suggests she used "unscientific methodologies" in her own report. It is no basis to exclude her testimony.

#### 2. Dr. Weiss Smith Does Not Need To Replicate Dr. Blume's Data To Validate Her Own Expert Opinions

Dr. Weiss Smith's decision not to replicate Dr. Blume's work provides no basis to exclude her opinions. Yet, Plaintiff asserts that "since [Dr. Weiss Smith] did not take any steps to confirm the data that formed the basis of Plaintiff's charts and Dr. Blume's expert opinions," Dr. Weiss Smith "should not be allowed to opine on the accuracy, reliability, or methodology of Dr. Blume's charts or opinions." Dr. Weiss Smith will not opine on whether Dr. Blume's calculations are correct. But she can offer expert opinions on the deficiencies in the underlying methodologies Plaintiff used to obtain those numbers and the improper inferences that Plaintiff draws from the numbers.

## III. PLAINTIFF MISCHARACTERIZES MINOR MISTAKES AND DISTORTS FACTS TO BOLSTER HER EXCLUSON ARGUMENT

Plaintiff presents a number of frivolous arguments, based on minor mistakes in Dr. Weiss Smith's reports, alleging she is "spinning a false perception" regarding the data, i.e., that she is lying. (*See* Pl.'s Memo. [90] at 2.) This baseless challenge to Dr. Weiss Smith's intellectual and scientific honesty is a shallow attempt to mislead the Court into discrediting and disqualifying this highly regarded and accomplished researcher.

### A. Dr. Weiss Smith Did Not Destroy the Data That Formed the Basis of Her Opinions, and Defendants Have Agreed To Produce All Data That She Read, Reviewed, or Considered

Plaintiff misconstrues the meaning of the "source data" that was used to form Dr. Weiss Smith's opinions when asserting that Dr. Weiss Smith "threw away" her data. To analyze the intentional self-injury, self injurious behavior, self-injurious ideation, suicidal behavior, and suicide FDA AERS data, Dr. Weiss Smith used a commercially available program, called QScan, which allowed her to search, download, and perform various analyses of the AERS data. The data downloaded from QScan are voluminous, and, given that Dr. Weiss Smith runs numerous

QScan queries as part of her everyday profession, storage of these massive data is not feasible. Thus, Dr. Weiss Smith created summary data through Excel spreadsheets, which she stored on her computer. After creating the summary data, Dr. Weiss Smith deleted the QScan source data from her computer.

However, the source data are easily retrievable from QScan. This is how Dr. Weiss Smith performs analyses of the AERS data in her regular professional work. At her deposition, Dr. Weiss Smith clearly stated that she did not keep the "source data" on her computer, but Plaintiff's counsel did not explore the whereabouts of the Excel spreadsheets. (Ex. D, Weiss Smith Dep. at 321:11-322:24.)

Defendants have agreed, pursuant to Rule 26, to produce all of Dr. Weiss Smith's source data (which includes a listing of each individual completed suicide or suicide attempt used in Dr. Weiss Smith's analysis) as well as the Excel spreadsheets that she considered and which formed the bases for the plots she presented in her two reports. (*See* Ex. I, Email from Michael Wasicko to Keith Altman.) Because there are no unproduced data that Dr. Weiss Smith read, reviewed, or considered, this point is moot.

### B. Despite Typographical and Other Minor Errors in Her Report, Dr. Weiss Smith Performed the Analyses Supporting Her Expert Opinions with Scientific Rigor

A smattering of typographical errors does not negate the fact that Dr. Weiss Smith met *Daubert*'s standards and performed the analyses supporting her opinions with the same scientific rigor that she uses in her profession. Plaintiff misconstrues *Daubert*' s definition of "scientific rigor," which is designed "to make sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996). Under *Daubert* and its progeny, courts are to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526

U.S. 137, 152 (1999). "[S]cientific rigor" means that "[e]xperts must show that their conclusions were reached by methods that are consistent with how their colleagues in the relevant field or discipline would proceed to establish a proposition were they presented with the same facts and issues." Reference Manual on Scientific Evidence, 26 (2nd ed. 2000). It is directed to the substance of the expert's opinion, not the manner in which she may have memorialized that opinion.

The mere fact that there were typographical errors or mistakes in her report, which Dr. Weiss Smith openly acknowledged at her deposition, does not render the underlying data or Dr. Weiss Smith's opinions unreliable. Plaintiff asserts that Dr. Weiss Smith's report is "rife with mathematical errors." (Pl.'s Memo. [90] at 15-16.) Yet, Plaintiff only points out a handful of percentage calculations that Dr. Weiss Smith performed incorrectly and one incorrect citation.[6] (*Id.* at 14-17.)[7] At her deposition, Dr. Weiss Smith distinguished the preparation of a litigation expert report from the preparation of a manuscript for a peer-reviewed journal:

> Q: One question of the witness before we conclude. Very early in the deposition Mr. Altman asked you a question regarding the scientific rigor in which you prepared your report and you stated that you used the same, I'll paraphrase, it, the same scientific rigor that you would use in doing your other professional work except you didn't have as many hands to look at the references, what did that mean?
>
> A: It means that this did not go through a formal peer review process. So if I write a paper, one, I'll have usually many co-authors. So everyone gets to review that and then I have a -- an editor in-house that will go through and edit.

---

[6] Plaintiff misconstrues the citation made by Dr. Weiss Smith. (Pl.'s Memo. [90] at 17.) Dr. Weiss Smith correctly quoted but miscited the author of a section from peer-reviewed literature that stands for the proposition that dechallenge/rechallenge does not prove a causal relationship for events such as depression. Plaintiff incorrectly asserts in her motion that a sentence excluded from Dr. Weiss Smith's report regarding *causality assessments* between a different drug (isotretinoin) and psychiatric events "substantially qualifies the first sentence." *Id.* However, the sentence that Plaintiff asserts that Dr. Weiss Smith should have quoted actually stands for an entirely different proposition, one for which Dr. Weiss Smith was not even providing an opinion. This is yet another example of Plaintiff distorting the record.

[7] It is worth noting that Dr. Weiss Smith included in her report the raw data for the percentage calculations Plaintiff now criticizes. (*See* Ex. A, Sheila Weiss Smith, Ph.D., November 4, 2008, Report. at 28.) This clearly shows no attempt on the part of Dr. Weiss Smith to deceive this court or a jury.

And then when I submit it to a journal for publication, it gets sent out to at least two, three, four peers that go through every aspect of the paper.

Q: In that process from time to time do they find typos and errors within the draft manuscript?

A: No matter how many times you write and rewrite it, there's always something, yes. They are noticed. Then also if it's accepted the journal has editorial staff that again go through it and sometimes you'll find them.

(Ex. D, Weiss Smith Dep. at 329:19-330:16.)

The Supreme Court has made clear that "reliable" relates "to the scientific context," in particular the characteristics of scientific methodology. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590-92 (1993). Typographical errors and mathematical miscalculations merely "go to the weight, not the admissibility" of expert opinions. *Baldwin v. Bader*, 539 F. Supp. 2d 443, 446 (D. Me. 2008); *see also Computer Assocs. Int'l v. Quest Software, Inc.*, 333 F. Supp. 2d 688, 694-95 (N.D. Ill. 2004) (holding mathematical and typographical errors in expert report went to weight not admissibility). Errors in the report do not warrant exclusion of the testimony. "Typographical errors do not necessarily reduce the evidentiary value of this general testimony and therefore do not require its exclusion." *Smith v. Wal-Mart Stores, Inc.*, 537 F. Supp. 2d 1302, 1329 n.25 (N.D. Ga. 2008). Likewise, "[a] typographical error appearing in an expert report might lead a fact-finder to conclude that the expert is sloppy, but it does not render an expert's opinion unreliable and thus inadmissible." *DePuty v. Lehman Bros., Inc.*, 345 F.3d 494, 506 (7th Cir. 2003). As such, Plaintiff's attempt to exclude the testimony of Dr. Weiss Smith based on typographical errors and miscalculations should be denied.

## IV. PLAINTIFF'S ARGUMENTS SUPPORT EXCLUDING THE TESTIMONY OF HER OWN EXPERT, DR. CHERYL BLUME

Plaintiff strenuously asserts that Dr. Weiss Smith's lack of clinical education or training precludes her from opining that "Plaintiffs' interpretation of the post-marketing adverse event data is flawed" because the opinion implies an "expertise to interpret the adverse events." (Pl.'s Memo. [90] at 5.) But Plaintiff cannot make this argument without first

conceding that her own expert, Dr. Cheryl Blume, is unqualified to render opinions on Defendants' interpretation of the post-marketing adverse event data. Dr. Blume is not a physician and has no clinical education or training. She has a Ph.D. in pharmacology but is not a pharmacoepidemiologist or an epidemiologist. Lacking any clinical expertise, she still filed a 200+ page report, most of which evaluates individual adverse event reports, and reviews individual patient narratives to support opinions on patient outcomes that are essentially "clinical." She bases her opinions on Neurontin post-market adverse event data almost exclusively on anecdotal adverse events analyzed by Plaintiff's attorney of record, Mr. Keith Altman. Should the Court exclude Dr. Weiss Smith's testimony because she lacks a clinical background, then it must also exclude Dr. Blume's testimony for the same reason.

Plaintiff's argument that Dr. Weiss Smith should be excluded from testifying because she "simply relied upon a summary prepared by Defendants for the FDA in response to the FDA suicide inquiry" cannot be reconciled with Dr. Blume's admission that she relied heavily on Mr. Altman to prepare much of her report. (Pl.'s Memo. [90] at 10.) Dr. Blume further concedes that she was not capable of verifying Mr. Altman's work and her general causation opinion would be the same even if the tables that he prepared were inaccurate. (*See* Ex. J, Cheryl Blume Dep. at 50:16-51:6, 53:24-54:9, 86:22-24, 88:22-89:7, 91:21-92:12, 102:17-21.)

In contrast, as discussed above, Dr. Weiss Smith, using an FDA-approved protocol, relied on Pfizer's non-litigation summaries of Neurontin clinical trial data. She also relied on summaries of post-market data prepared at FDA's request. Plaintiff is free to challenge the content of those summaries, but there is no basis to exclude Dr. Weiss Smith merely because she relied on those data. If anything, Plaintiff's argument casts greater doubt on the admissibility of Dr. Blume's testimony than Dr. Weiss Smith's.

## CONCLUSION

For the foregoing reasons, Plaintiff's motion should be denied.

Dated: April 27, 2010

Respectfully submitted,

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP

By: /s/ Mark S. Cheffo
Mark S. Cheffo

Four Times Square
New York, NY 10036
Tel: (212) 735-3000

-and-

NEAL & HARWELL, PLC

By: /s/ Gerald D. Neenan
Aubrey B. Harwell, Jr., No. 002559
W. David Bridgers, No. 016603
Gerald D. Neenan, No. 006710

2000 One Nashville Place
150 Fourth Avenue, North
Nashville, TN 37219
(615) 244-1713
(615) 726-0573 (fax)

*Attorneys for Defendants Pfizer Inc and Warner-Lambert Company LLC*

**CERTIFICATE OF SERVICE**

I hereby certify that on this the 27th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Andrew G. Finkelstein, Esq.
Kenneth B. Fromson, Esq.
Finkelstein & Partners, LLP
1279 Route 300
Newburg, NY 12550

Charles F. Barrett, Esq.
Barrett & Associates, P.A.
6718 Highway 100, Suite 210
Nashville, TN 37205

Dara G. Hegar, Esq.
Ken S. Soh, Esq.
Maura Kolb, Esq.
Robert Leone, Esq.
W. Mark Lanier, Esq.
Lanier Law Firm
6810 FM 1960 West
Houston, TX 77069

/s/ Gerald D. Neenan
Gerald D. Neenan